Drug	# of pts with MI	Total # of pts.	Pt months Exposure Time	MI rate per 1000 pt – yrs
Nifedipine GITS	4	2,629	9,247	5.2
Amlodipine	22	25,853	68,675	3.9

In a subset of comparative trials the incidence of MI among 1372 pts receiving nifedipine GITS was 3.3/1000 pt-years while among 621 pts receiving active agents other than CCB's it was 5.1/1000 pt-years (p = NS); and the incidence of MI among 3748 patients receiving amlodipine was 4.3/1000 pt-years while among 927 patients receiving active agents other than CCB's it was 2.2/1000 pt-years (p = NS). These data support the concept that the long-acting CCB's nifedipine GITS and amlodipine are safe for treating hypertension.

2:45

760-4 Heart Rate Lowering Calcium Antagonists (HRL-CA) in Hypertensive Post MI Patients

Franz H. Messerli, William E. Boden, Jørgen Fischer Hansen, Kenneth B. Schechtman. *Ochsner Medical Institutions, New Orleans, LA; Washington University, St. Louis, MO*

Two recent publications (JAMA 1995;274:620 and Circulation 1995;92:1326) have cast doubt on the safety of CAs. Previous meta-analysis (Am J Cardiol 1991;67:1295) has shown that in the post MI patient not all CAs are created equal and that some dihydropyridine CAs may be detrimental, whereas HRL-CAs (diltiazem/verapamil) may be beneficial. The present data are based on a post hoc analysis of pooled data obtained from 5,677 post MI patients, randomized to either a HRL-CA or placebo in the first and second Danish Verapamil Infarction Trials (DAVIT I and II) and the Multicenter Diltiazem Post Infarction Trial (MDPIT). Mean follow-up was 550 ± 376 days, all-cause mortality was 16.3% in hypertensives (HTS) and 12.0% in normotensives (NTS), and event rates (death or MI) were 24.4% vs 17.8%. Mortality was slightly lower in patients on HRL-CAs than in those on placebo in both HTS (15.1% vs 17.5%) and NTS (11.7% vs 12.4%). However, cumulative event rates were significantly reduced by HRL-CAs in HTS as follows:

	Hypertensive		Normotensive	
HRL-CA	142/667	21.4%	372/2159	17.2%
Placebo	180/658	27.4%	402/2190	18.4%
p =	0.004		0.319	

After adjusting for age, gender, a history of previous MI, and diabetes using Cox regression, the use of HRL-CAs in HTS was associated with significantly reduced event rates (p = 0.016), adjusted risk ratio 0.76 (95% confidence bounds ranging from 0.61–0.95). We conclude that treatment with HRL-CAs in HTS post MI patients significantly diminishes event rate whereas little effect is seen in NTS subjects. These data with HRL-CAs are in contrast with other reports on dihydropyridine CAs showing no effect or an increase in events.

3:00

760-5 Effect of Gender on Relative Efficacy of Isradipine vs Hydrochlorothiazide for Reduction of Left Ventricular Mass

Vasilios Papademetriou, John Gottdiener, Puneet Narayan. *Veterans Affairs and Georgetown University Medical Centers, Washington, D.C.*

In patients with hypertensive LVH, reduction of LV mass is a desirable goal of drug therapy. However, comparative data between men and women is scarce. In this 18 center single-blind, randomized trial we compared isradipine (ISR) and hydrochlorothiazide (HCTZ) in 134 pts (age 57 ± 10 years, BP 164 ± 21/110 ± 10 mm Hg, echo LVM 345 ± 80 g ASE, 26 women). At 3 and 6 months of therapy decreases in septal and posterior wall thickness were similar between ISR and HCTZ. However, decrease in LV mass was greater with HCTZ (–43 g) vs ISR (–11 gr, P < 0.01) due to decrease in diastolic LV size (–2.8 mm). Comparing the response of men and women the following results were obtained:

LV Mass Change from Baseline

	Isradipine		HCTZ	
	Men (n = 74)	Women (n = 15)	Men (n = 34)	Women (n = 11)
3 Mo	–10.8*	–17.3	–36.3**	–7.6
6 Mo	–7.3	–21.1	–48.1**	–15.3
2 Wk Post	–8.2	0.8	–30.6**	–2.9

*P < 0.03, **P = 0.001; P = Change from baseline

It is concluded that LV mass reduction with HCTZ was limited to men. The response to ISR was small overall with a trend of greater LV mass reduction in women. Further studies are needed to confirm this observation.

3:15

760-6 Gender Differences in the Relationship Between Diastolic Function and Oxygen Consumption in Hypertensive Subjects

Ali G. Gharavi, Joseph A. Diamond, Neil L. Coplan, Adam Y. Goldman, Jeffrey S. Jhang, Marilyn Steinmetz, Robert A. Phillips. *Mount Sinai School of Medicine & Lenox Hill Hospital, New York, NY*

Previous studies have suggested that diastolic function is a major determinant of exercise capacity and oxygen consumption (VO2) in hypertension. To further evaluate the effects of gender on determinants of VO2 (cc/kg/min), we studied 48 sedentary, asymptomatic, untreated hypertensive subjects (M = 31, F = 17; office BP = 165/107 + 19/12). All subjects underwent: 1) 24 hour ambulatory blood pressure monitoring, 2) resting 2-D directed M-mode and LV inflow Doppler echocardiography, 3) graded maximal bicycle ergometry with VO2 measurement. There were no gender differences in age, BMI, office and 24 hr BP, resting heart rate, peak early (E), late (A) mitral inflow velocities and A/E ratio. Women had significantly lower LV mass, peak VO2 and VO2 at anaerobic threshold. In men, peak VO2 was inversely related to peak A ($r = -0.62$, $p < 0.0005$), and age ($r = -0.43$, $p < 0.02$). On stepwise multiple regression analysis, only peak A remained significantly related to peak VO2 in men ($r^2 = 0.39$, $P < 0.001$). In women, there was no relationship between any measure of diastolic function and VO2 at various levels of exercise. On multiple regression analysis, only peak exercise BP was directly related to peak VO2 in women ($r^2 = 0.33$, $P < 0.03$). There are significant gender differences in determinants of VO2 in hypertensive subjects. Doppler determined diastolic function is a major predictor of VO2 in men but not in women.

761 Vein Graft Interventions

Tuesday, March 26, 1996, 4:00 p.m.–5:30 p.m.
Orange County Convention Center, Room 224

4:00

761-1 Randomized Trial of Coronary Stent and Balloon Angioplasty in the Treatment of Saphenous Vein Graft Stenosis

John S. Douglas, Jr., Michael P. Savage, Steven R. Bailey, Carl J. Pepine, Jeffrey A. Wemer, Paul A. Overlie, Jeffrey A. Brinker, David Fischman, Sheldon Goldberg, Spencer B. King III, SAVED Trial Investigators. *Emory University School of Medicine, Atlanta, GA*

To compare the outcome of Palmaz-Schatz coronary stent (S) with balloon angioplasty (B), 215 patients with clinical evidence of ischemia and focal de novo vein graft stenoses were randomized at 12 centers. Demographic and clinical features of S and B groups were similar. Clinical events at 30 days are reported in all patients and angiographic follow-up in 83% of eligible patients (last patient will be eligible for follow-up angio in December 1995). Procedural success without cardiac complication was achieved in 90% of S and 78% of B patients (P < 0.015).

	Stent	Balloon	P
Clinical Events (%) at 30 days (N = 215)			
Death	4	3	NS
Non-QMI/Q wave MI	2/2	8/1	0.059/NS
CABG	2	4	NS
Femoral repair	3	2	NS
Transfusion	11	1	0.003
Quantitative Angiography (N = 152 with 6 Month Follow-up)			
Baseline MLD (mm)	0.90	0.95	NS
Postprocedure MLD (mm)	2.81	2.16	<0.0001
MLD at 6 months (mm)	1.72	1.50	NS
Immediate gain (mm)	1.90	1.19	<0.0001
Late loss (mm)	1.10	0.66	0.005
Net gain (mm)	0.79	0.51	0.069

Thus, stenting was associated with a higher procedural success rate, a larger improvement in MLD, and a trend toward fewer non-Q MI, but significantly more transfusions. Interim analysis of late angiographic follow-up demonstrates significantly greater late lumen loss but a trend toward greater net gain after stenting. Complete six-month angiographic and clinical outcomes will be reported.